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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,892	12/01/2000	Jerry Pelletier	073406-0302	3660

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FOLEY & LARDNER  
P.O. BOX 80278  
SAN DIEGO, CA 92138-0278

EXAMINER
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PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/727,892</b>	Applicant(s) <b>Pelletier et al</b>	Examiner <b>Portner</b>
	Art Unit <b>1645</b>	[Redacted]	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --</i>			
<b>Period for Reply</b>			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Apr 21, 2003</u>			
2a) <input checked="" type="checkbox"/> This action is <b>FINAL</b> .		2b) <input type="checkbox"/> This action is non-final.	
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>112 and 119-137</u> is/are pending in the application.			
4a) Of the above, claim(s) <u>132 and 134-137</u> is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>112, 119-131, and 133</u> is/are rejected.			
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.			
8) <input checked="" type="checkbox"/> Claims <u>112 and 119-137</u> are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input checked="" type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. <p style="margin-left: 20px;">Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p>			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. <p style="margin-left: 20px;">If approved, corrected drawings are required in reply to this Office action.</p>			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). <p style="margin-left: 20px;">a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Certified copies of the priority documents have been received.</li> <li>2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</li> <li>3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol>			
<p style="margin-left: 20px;">*See the attached detailed Office action for a list of the certified copies not received.</p>			
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). <p style="margin-left: 20px;">a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p>			
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
<b>Attachment(s)</b>			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>22</u>		6) <input type="checkbox"/> Other: _____	

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## **DETAILED ACTION**

Claims 112, 119-137 are pending.

New claims 119-137 were submitted.

All previously pending claims except claim 112 were canceled.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Allowable Subject Matter***

2. Claim 112 defines over the prior art of record and would be allowable upon amendment of the claim to obviate the rejection under 35 U.S.C. 112, second paragraph set forth below.

### ***Election/Restriction***

3. Newly submitted claims 132 and 134-137 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly submitted method claim 132, utilizes:

bacteriophage polypeptide ORF25, and

first and second dnaN polypeptides the first being any dnaN polypeptide and the second being S.aureus DNA directed DNA polymerase III beta subunit.

The newly submitted method claims 134-137 utilize:

any bacteriophage polypeptide;

any dnaN, (claim 136) additionally utilizes a second S.aureus dnaN polypeptide;

(claim 137) additionally utilizes a bactericidal or bacteriostatic assay to assess the activity of the test compound.

These combinations of reagents are not the elected invention directed to methods that utilize ORF 25, SEQ ID NO 99 together with a single dnaN to screen test compounds that inhibit binding between ORF25 and the dnaN polypeptides.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 132, and 134-137 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Objections and Rejections Withdrawn***

4. In light of the submission of Applicant's stamped post-card and the accompanying Table 1-8, the specification is no longer objected to under 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: The meanings of data referred to be in Tables 1-8, in light of the fact that the instant specification does not have any data in Tables labeled 1-8; no tables having been submitted, the instant specification, is unclear. See Page 30, lines 25-30 and page 31, lines 1-17. At various locations, the specification refers to information in tables, but the information has not been set forth in any tables and therefore is not clear; the meaning of the narrative which refers to the tables is unclear.
5. Claims 81-96 , 111 rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, credible and substantial asserted utility or a well established utility for the elected invention of bacteriophage 44AHJD open reading frame 25 product fragments, homolog frgments and structural mimics of the open reading frame 25 product; the claims have been canceled.
6. Claims 81-96 , 111 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID Nos: 99 for ORF25

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and SEQ Id No 2 for S.aureus dnaN and therefore the written description is not commensurate in scope with the claims drawn to mimetic,a corresponding isolated,”... “or a homologous product of a S.aureus dnaN gene” which would include by definition provided in the instant specification a “structural mimetic of a bacteriophage 44AHJD ORF25 product or biologically active fragment (fragments are defined at page 4, lines 10-21 to include fragments from 5 amino acids in length)” or a “gene homologous to a gene from a plant pathogen”; in light of the claims having been canceled.

7. Claims 81-96,111 rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, credible and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.; ; in light of the claims having been canceled.

8. Claims 81-93 and 112 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in light of the cancellation of claims 81-93 and the amendment of claim 112.

9. Claims 81-86, 92-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Loessner et al (August 1999, Journal of Bacteriology), in light of the cancellation of claims.

#### *Objections and Rejections Maintained*

10. The disclosure objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See at least page 22, lines 29-30; page 23, lines 2-4; page 31, line 27; page 59, lines 26-30 and page 60, lines 1-9. All hyperlinks should be removed wherever they appear in the instant specification.

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*V&P  
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11. Claims 119-~~125~~<sup>131</sup>,133 as previously applied to claims 81-96 , 111 are rejected under 35 U.S.C. 112, first paragraph (written description of a representative number of species to enable the claimed genus), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID Nos: 99 for ORF25 and SEQ Id No 2 for S.aureus dnaN and therefore the written description is not commensurate in scope with the claims drawn to mimetic,a corresponding isolated,"... "or a homologous product of a S.aureus dnaN gene" which would include by definition provided in the instant specification a "structural mimetic of a bacteriophage 44AHJD ORF25 product or biologically active fragment (fragments are defined at page 4, lines 10-21 to include fragments from 5 amino acids in length)" or a "gene homologous to a gene from a plant pathogen".

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***Response to Amendment***

12. The Declaration of Dr. Michael Dubow under 37 CFR 1.132 filed April 21, 2003 is insufficient to overcome the rejection of claim~~119-131, 133~~<sup>131</sup> based upon 35 U.S.C. 112, first paragraph, (written description) as set forth in the last Office action because:

- a. The data presented in paragraph 5, is directed to fragments of open reading frames that are not ORF 25; the embodiment now claimed.
- b. Paragraphs 6-8 discuss a method for the future identification of additional inhibitory bacteriophage proteins. The claimed method recites ORF25 variants and fragments, and the Declaration proposes to identify them for use in the claimed method. The arguments set forth in Declaration paragraphs 6-8 primarily focus on what could be identified and not the ORF25 variants/fragments, and dnaN variants/fragments/homologs now recited. The variants and fragments discussed in paragraphs 6-8 have yet to be identified, thus providing evidence that Applicant did NOT have possession of the variants, fragments and homologs of ORF25 and dnaN

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at the time of filing. At no time did the examiner raise any issues with respect to the structure or function of the test compound with respect to a lack of written description for enablement, but focused on the lack of enablement due to a lack of written description of variants, fragments and homologs of ORF25, and dnaN of *S.aureus*.

c. Paragraph 9 discusses Dna-I, DnaG and sigma-70 fragments; these are not the ORF25 or dnaN variants/fragments/homologs recited in the instantly claimed invention. The data presented in paragraph 9 is not commensurate in scope with the instantly claimed invention.

d. Paragraph 10 addresses the issue of identifying bacteriophage fragments and bacterial fragments of polypeptides that are not ORF25 using routine experimentation to produce and evaluate them; this is not the claimed invention.

The instantly claimed invention is directed to a method of screening for inhibitors that competitively displace bacteriophage ORF25 polypeptide from specifically binding to dnaN polypeptide; the method screens for inhibition of binding. The data presented with respect to the production of fragments/variants/homologs of other polypeptides that are not ORF25 and dnaN polypeptides, does not provide evidence that Applicant had possession of a representative number of species at the time of filing for the instantly claimed genus of methods that utilize fragments/variants/homologs of ORF25 and *S.aureus* dnaN to identify inhibitors.

The data presented is not commensurate in scope with the instantly claimed invention and present data for the identification of reagents to be used in the future for screening inhibitors of dnaN. The data presented which teaches means for the identification of futures reagents provides support for the Examiner's rejection of the claims under 35 U.S.C. 112, first paragraph (written description). The rejection is maintained for reasons of record in paper number 19, pages 12-15 and arguments set forth herein.

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***Response to Arguments***

13. Applicant states the that the “electronically accessible addresses” are “not in browser-executable form.”
14. It is the position of the examiner that the addresses that remain in the specification still constitute addresses that define browser-executable code; the objection to the specification is maintained for reasons of record.
15. The rejection of claims 119-131,133 as previously applied to claims 81-96 , 111 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID Nos: 99 for ORF25 and SEQ Id No 2 for S.aureus dnaN and therefore the written description is not commensurate in scope with the claims drawn to mimetic,a corresponding isolated,”... “or a homologous product of a S.aureus dnaN gene” which would include by definition provided in the instant specification a “structural mimetic of a bacteriophage 44AHJD ORF25 product or biologically active fragment (fragments are defined at page 4, lines 10-21 to include fragments from 5 amino acids in length)” or a “gene homologous to a gene from a plant pathogen”  
is traversed on the grounds that “Indeed, one can readily utilize the information provided in the present application to identify derivatives of bacteriophage proteins with inhibitory activity that are still capable of specifically interacting with a specific bacterial target (Amendment page 12, last paragraph, first sentence).  
16. It is the position of the examiner that the written description rejection made of record was over claims that encompass the utilization of products not described. A method of screening for derivative proteins does not show possession of the derivative proteins at the time of filing. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that “applicant must convey with

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reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed.*” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA...’requires a precise definition, such as by structure, formula, chemical name, or physical properties’, not a mere wish or plan for obtaining the claimed chemical invention”. The rejection is maintained for reasons of record in paper number 19, paragraph 8.

17. Applicant traverses the rejection of claims 119-125, 127-131,133 as previously applied to claims 81-96 , 111 under 35 U.S.C. 112, first paragraph, (written description) be asserting that the references cited for lack of written description of variants and fragments do not meet the recited claim limitations of newly submitted claims, which require the compound to bind specifically.
18. It is the position of the examiner that the references cited in the rejection of the claims under 35 U.S.C. 101, also serve to provide support for the basis of the rejection set forth under 35 U.S.C. 112, first paragraph written description rejection; the written description rejection sought to address the scope of the claims directed to variants, homologs and fragments; the fragments being defined to include polypeptides of 5 amino acids (see instant specification, page 4, lines 10-21).

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The cited references in paragraph 9, paper number 19, provided evidence that any fragment portion of ORF25 would not serve to identify inhibitors. The claims do not require the variants and fragments to evidence any specific biological activity. A suggestion for identifying variants, homologs and fragments for use in the claimed methods does not show possession of the reagents for use in the claimed method at the time of filing.

The rejection of the claims under 35 U.S.C. 112, first paragraph (scope of enablement based upon the lack of written description) is maintained for reasons of record in paper number 19, pages 12-15.

***New Claims/New Claim Limitations/New Grounds of Rejection***

***Claim Rejections - 35 U.S.C. § 112***

19. Claim 112, 119-131, 133 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 112, has been amended to recite the phrase “a protein:protein interaction”; this phrase lacks antecedent basis in the claim. Additionally, Claims 112 and 119-131, recite the phrases “wherein a reduction of said interaction is indicative that said test compound inhibits S.aureus DNA-directed DNA polymerase III beta subunit protein (claim 112)” and “wherein a reduction of said binding between said dnaN polypeptide and said 44AHJD ORF25 polypeptide, (claims 119-131, 133)” respectively. How is a reduction of interaction or binding indicative that said test compound inhibits S.aureus DNA-directed DNA polymerase III beta subunit protein?

The test compound is not defined to evidence any specific function or structure and could interact with the 44AHJD ORF25 polypeptide or SEQ ID NO. 99 or S.aureus DNA directed polymerase III beta subunit; how is a reduction in interaction or binding only indicative of S.aureus DNA-directed DNA polymerase III beta subunit protein inhibition? Claims 112 and

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119-131 and 133 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: an essential step that defines the interaction of the test compound with the *S.aureus* DNA-directed DNA polymerase III beta subunit protein which shows that the test compound is a specific inhibitor of *S.aureus* DNA-directed DNA polymerase III beta subunit protein and not the polypeptide of SEQ ID NO. 99 or the 44AHJD ORF25 polypeptide.

Claim 119 recites the phrase “a dnaN polypeptide”; this phrase lacks antecedent basis in the preamble which recites the phrase *S.aureus* dnaN. A compound that would bind to any dnaN polypeptide would not necessarily correspond to inhibiting to *S.aureus* dnaN as recited in the preamble of the claim. Clarification of how any dnaN polypeptide that is not *S.aureus* dnaN would serve to interact with, bind to or identify an inhibitor of *S.aureus* dnaN protein is requested.

Claims 128 and 130 directly or indirectly depend from claim 119 and recite the phrase “said binding determination comprises detecting a protein:protein interaction” and “wherein detection of said protein:protein interaction”, respectively. How are claims 128 and 130 further limiting of claim 119 that determines a reduction in the binding? Binding is a type of interaction. Claim limitations directed to any type of interaction broadens the scope of the dependent claims; the dependent claims are not limited to specific binding, but only an interaction. What additional type of interaction is being determined in the method of claims 128 and 130? In order to determine a reduction in binding, a protein:protein interaction must have already been determined. Clarification is requested.

*Conclusion*

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

July 10, 2003

*LYNETTE R. F. SMITH*  
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